

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
15 September 2005 (15.09.2005)

PCT

(10) International Publication Number
WO 2005/084666 A1

(51) International Patent Classification: A61K 31/41

(21) International Application Number:
PCT/US2005/006043

(22) International Filing Date: 28 February 2005 (28.02.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/549,420 2 March 2004 (02.03.2004) US

(71) Applicant (for all designated States except US):
ABEILLE PHARMACEUTICALS, INC. (US/US); 116
Village Boulevard, Suite 200, Princeton, NJ 08540-5700
(US).

(72) Inventor; and

(73) Inventor/Applicant (for US only): BORSADIA, Suresh
(US/US); Abeille Pharmaceuticals, Inc., 116 Village
Boulevard, Suite 200, Princeton, NJ 08540-5700 (US).

(74) Agent: JACKSON, Arthur; Law Offices of Arthur E.
Jackson, P.O. Box 88, Hopewell, NJ 08525 (US).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,
MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,
PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ,
TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA,
ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO,
SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN,
GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: CO-FORMULATIONS OF KITS OF BIOACTIVE AGENTS

(57) Abstract: Provided, among other things, is a formulation or kit comprising: (a) a pharmaceutically effective dosage of one or more a glucose-level-controlling bioactive agents selected from an α -glucosidase inhibitor, sulfonylurea, meglitinide, thiazolidinediones, biguanide, insulin, dual PPAR α/γ agonist, PPAR γ agonist or insulin secretagogue; and (b) a pharmaceutically effective dosage of (i) one or more of an antihypertensive bioactive agent selected from an ACE inhibitor, calcium channel blocker, beta blocker, angiotension II receptor antagonist or diuretic, or (ii) one or more of an anti-dyslipidemia bioactive agent selected from a HMG-CoA reductase inhibitor, bile acid sequestrant, fabric acid derivative, sterol, cholesterol absorption inhibitor, MTP inhibitor or nicotinic acid derivative; wherein: in the case of (i) a combination of a first bioactive agent of group (a) that is metformin with a second bioactive agent of group (b), or (ii) a combination of a first bioactive agent of group (a) that is a thiazolidinedione or dual PPAR α/γ agonist with an angiotension II receptor antagonist, one or more of the following applies: (I) one of the first bioactive agent or the second bioactive agent is formulated for sustained release, and the other is formulated for immediate release, each formulated for once-a-day dosing; or (II) the co-formulation or kit comprises (A) a biguanide and a thiazolidinedione and (B) one or more group (b) bioactive agents.